

REMARKS

Specification

The specification has been amended to recite the subject matter of original claims 40-43. Originally filed claims are deemed part of the disclosure of the specification. See *In re Gardner*, 475 F.2d 1389, 1391, 177 U.S.P.Q. 396, 397 (CCPA 1973); see also Manual of Patent Examining Procedure (MPEP), Eighth Edition, Latest Revision July 2010, section 2163(I) at page 2100-172, right column, tenth line from the bottom, to page 2100-173, left column, line 2; and page 2100-174 to 2100-176, in particular, page 2100-175, left column, second paragraph, lines 9-14. No new matter has been added.

Claims

Claims 4, 6, 9-14, 44 and 45 were pending in this application before entry of the amendments made herein.

Claims 4, 9, 10 and 12-14 have been amended for purposes of clarity. In particular, claims 4 and 12-14 have been amended to delete the terms “preventing,” “prevention,” “prevented,” “delaying,” “delay” and “delayed.”

Claim 4 also has been amended to recite a method for treating a neoplasm which expresses ErbB-3. Support for the amendments can be found in the specification at, *inter alia*, page 23, lines 9-10.

In addition, claim 4 has been amended to recite a method comprising administering, alternatively, an effective amount of a nucleic acid encoding the ErbB-3 protein, and dependent claims 9 and 10 have been amended accordingly. Support for the amendments can be found in the specification at, *inter alia*, page 3, lines 23-28; page 12, lines 5-10; and page 13, lines 3-11.

New claims 46-77 have been added. Support for the new claims can be found in the specification as indicated in the table below.

| New Claim | Support |
|-----------|---|
| 46 | Page 14, lines 2-5 |
| 47 | Original claim 7; page 14, lines 11-13 |
| 48 | Original claim 8; page 14, lines 13-15 |
| 49 | Original claim 15; page 4, lines 1-7; page 18, lines 12-23 |
| 50 | Original claim 16; page 15, lines 7-9; page 18, lines 24-26 |

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| 51 | Original claim 17; page 15, lines 7-9; page 18, lines 24-26 |
| 52 | Original claim 18; page 19, line 15 |
| 53 | Original claim 19; page 19, lines 15-16 |
| 54 | Original claim 20; page 19, lines 16-17 |
| 55 | Original claim 21; page 19, lines 18-22 |
| 56 | Original claim 22; page 4, lines 8-13; page 19, lines 23-28 |
| 57 | Original claim 23; page 4, lines 14-22; page 20, lines 4-12 |
| 58 | Original claim 24; page 20, lines 12-13 |
| 59 | Original claim 25; page 5, lines 1-3; page 21, lines 8-20 |
| 60 | Original claim 26; page 21, lines 21-22 |
| 61 | Original claim 27; page 5, lines 1-3; page 21, lines 24-30 |
| 62 | Original claim 28; page 21, line 30 to page 22, line 1 |
| 63 | Original claim 29; page 22, lines 4-12 |
| 64 | Original claim 30; page 22, lines 13-14 |
| 65 | Original claim 31; page 22, lines 13-14 |
| 66 | Original claim 32; page 22, lines 17-18 |
| 67 | Original claim 33; page 22, lines 17-18 |
| 68 | Original claim 34; page 21, lines 21-22 |
| 69 | Original claim 35; page 21, lines 22-23 |
| 70 | Original claim 36; page 22, lines 1-2 |
| 71 | Original claim 37; page 22, lines 2-3 |
| 72 | Original claim 38; page 17, lines 11-15 and 23-24 |
| 73 | Original claim 39; page 17, lines 11-15 and 23-24 |
| 74 | Original claim 40 |
| 75 | Original claim 41 |
| 76 | Original claim 42 |
| 77 | Original claim 43 |

No new matter has been added by these amendments. Upon entry of the present amendment, claims 4, 6, 9-14 and 44-77 will be pending in the present application.

I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

Claims 4, 6, 9-14, 44 and 45 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement rejection. Specifically, the Examiner alleges that “the specification, while being enabling for a method for treating a neoplasm in a mammal, wherein the neoplasm expresses ErbB-3, comprising the administering to the mammal the claimed ErbB-3 extracellular domain proteins, does not reasonably provide enablement for said method for *preventing or delaying* a neoplasm or treating any *neoplasm that does not express ErbB-3*” (see Office Action, page 2, item 2).

Although Applicant disagrees, solely to expedite prosecution of this application, Applicant has amended claim 4 such that it no longer recites a method for preventing or delaying a neoplasm. Applicant also has amended claim 4 to recite a method for treating a neoplasm which expresses ErbB-3. Withdrawal of the rejection is respectfully requested.

II. INTERVIEW REQUEST

Applicant respectfully requests a telephonic interview with the Examiner to discuss the claim amendments made herein. In particular, Applicant wishes to discuss the recitation “a nucleic acid encoding said ErbB-3 protein” in claim 4 and new claims 47-77. The Examiner’s attention is respectfully directed to the Restriction Requirement mailed June 11, 2008, which required Applicant to elect one of five inventions¹, which allegedly do not relate

¹ The Restriction Requirement listed the following five inventions:

- Group I, original claims 1-14, drawn to the special technical feature of a method for preventing, treating or delaying neoplasm in a mammal, which method comprises administering to an mammal an effective amount of an **ErbB-3 protein**, or functional fragment thereof, whereby an immune response is generated against said neoplasm and said neoplasm is prevented, treated or delayed.
- Group II, original claims 1-14, drawn to the special technical feature of a method for preventing, treating or delaying neoplasm in a mammal, which method comprises administering to an mammal an effective amount of a **nucleic acid encoding an ErbB-3 protein**, or functional fragment thereof, whereby an immune response is generated against said neoplasm and said neoplasm is prevented, treated or delayed.
- Group III, original claims 15-21, 25, 26, 34, 35, 38, 40 and 41, drawn to the special technical feature of an **isolated nucleic acid fragment**, which isolated nucleic acid fragment comprises a sequence of nucleotides encoding: a) an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; a plasmid comprising the nucleic acid fragment, a cell comprising the plasmid, a method for producing an extracellular domain of ErbB-3 protein comprising growing the cell, a pharmaceutical composition, vaccine, or kit comprising the nucleic acid fragment, and a combination of the fragment with an anti-neoplasm agent.
- Group IV, original claims 22-24, 27, 28, 36, 37, 39, 42 and 43, drawn to the special technical feature of a substantially purified **protein or peptide**, which comprises: a) an extracellular domain of the ErbB-3

to a single general inventive concept under PCT Rule 13, and which allegedly lack the same or corresponding special technical features under PCT Rule 13.2. While Applicant elected Group I in the Response submitted September 5, 2009, Applicant wishes to now reintroduce into the instant application the subject matter of non-elected Groups II-V, i.e., original claims 1-14 (in part) and 15-43, which is recited in amended claim 4 and new claims 49-77, respectively. Applicant submits that the new claims recite the same technical feature recited in claim 4, and thus, relate to a single general inventive concept.

CONCLUSION

Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Date: September 8, 2010

Anthony C. Chen by [Signature]
Anthony C. Chen 38,673
(Reg. No.)
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; a conjugate comprising said protein or peptide and a facilitating agent; a pharmaceutical composition, vaccine, or kit comprising said protein or peptide; and a combination of said protein or peptide and an anti-neoplasm agent.

- Group V, claims 29-33, drawn to the special technical feature of **an antibody** which binds: to an epitope in an extracellular domain of the ErbB-3 protein, or functional fragment thereof, comprising an amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:3; b) to an epitope in an amino acid sequence comprising at least amino acid residues 24-81 of the amino acid sequence set forth in SEQ ID NO:14; or c) to an epitope in an amino acid sequence comprising at least amino acid residues 2-139 of the amino acid sequence set forth in SEQ ID NO:16; and a pharmaceutical composition comprising said antibody.